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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO. <i>12</i>
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EXAMINER

ART UNIT	PAPER NUMBER
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1771
DATE MAILED:

10
10/11/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/137,127	Applicant(s) WARD ET AL.	
	Examiner Christopher C. Pratt	Art Unit 1771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☐ Responsive to communication(s) filed on 31 July 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 11-25 and 62-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-8, 11-25 and 62-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☒ received.
2. ☐ received in Application No. (Series Code / Serial Number) _____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. Applicant's amendments and accompanying remarks filed 7/31/00 have been entered and carefully considered. Applicant's amendment is found to overcome the objection to the specification and claims, as well as the 112 indefinite rejection set forth in the last office action. Despite this advance, the amendments are not found to patently distinguish the claims over the prior art and Applicant's arguments are not found persuasive of patentability for reasons set forth herein below.

Drawings

2. In response to the requirement to furnish a drawing applicant has stated that an informal drawing was submitted, however no submitted drawings can be found in the case.

Claim Rejections - 35 USC § 112

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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5. Claims 1-8, 11-25 and 62-66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is also indefinite because it refers to a fibrous polymeric material and a recrystallized polymeric material consisting of the same polymer, but having different melting points. How can the same polymer have different melting points?

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-8, 11-25 and 62-66 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S.

Patent No. 6017834 in view of Bonfield et al (5017627). The claims of 6017834 disclose all elements of applicant's invention except for the use of a filler. The use of fillers such as apatite is common in the art and is taught by Bonfield et al.

Claim Rejections - 35 USC § 103

8. Claims 1-8, 11-25 and 62-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ward et al (6017834) in view of Bonfield et al (5017627).

Ward's patent is concerned with the creation of composite material used in bone prostheses. Said composite comprising molecularly oriented polymeric fibers and a recrystallized melt phase of the same polymer (abstract, col. 1-2, and lines 50-21). Ward does not seem to disclose the use of a filler.

Bonfield's patent is concerned with the creation of a composite material used in bone prostheses. Bonfield teaches the use of a polymeric composite comprising up to 80% of a particulate filler of hydroxyapatite (cols. 1-2, lines 59-24). It would have been obvious to a person of ordinary skill in the art to utilize the filler taught by Bonfield in the composite of Ward. Such a combination would have been motivated by the reasoned expectation of providing Ward's composite with reinforcement and enhanced stiffness, in order to strengthen the composite (col. 2, lines 13-15).

Ward discloses a fiber length under .5mm (col. 3, line 30).

Said composite is void free (col. 2, lines 3-5).

With respect to claims 11-21, the composite created by the combination of Ward and Bonfield would inherently have the properties claimed by applicant because said composite is composed of the same materials in the same amounts as claimed by applicant.

Ward discloses the use of a high modulus polyethylene anticipating the weight average molecular weight claimed by applicant (col. 3, lines 50-60).

With respect to claim 25, Ward discloses the process claimed by applicant (abstract).

9. Claims 1-6, 11-25 and 62-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turner et al (4662887) in view of applicant's admitted prior art (AAPA).

Applicant has amended independent claim 1 to include the limitation that the recrystallized melt phase contains only 5-50% by weight of the polymer in which the fibers are composed of. The wording of this new limitation renders the claims indefinite, as set forth above, however it appears that applicant intends for other materials to be included in said recrystallized melt phase.

Turner discloses a composite material comprising a particulate inorganic filler and a fibrous material (col. 3, lines 33-35). Turner does not explicitly state that said fibrous material is molecularly oriented, however, in view of AAPA it would have been obvious to a person ordinary skill in the art to molecularly orient the fibers. Such a modification would have been motivated by the reasoned expectation of providing Turner's fibrous material with increased stiffness and strength (p. 2, lines 11-15 of applicant's specification). Turner further discloses a recrystallized polymeric matrix, which binds the fibrous material and filler together, to be composed of different materials (cols. 2-3, lines 65-5). These materials are in amounts anticipating applicants

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claimed amounts (col. 3, lines 11-20). Turner does not explicitly teach said fibrous material to be composed of the materials in which the recrystallized polymeric matrix is composed of. Instead Turner teaches that the fibrous material may be **any** material and the only criteria set forth for the materials of the fibers is that they be compatible with the polymeric matrix (col. 3, lines 45-47). Turner then lists a number of preferred examples including an organic polymeric material (col. 3, line 53). It would have been obvious to a person of ordinary skill in the art to utilize one of the materials used to create the recrystallized matrix, PEEK for example, as the materials used to form the fibrous material. Such a modification would have been motivated by the reasoned expectation of utilizing a material which fulfills Turner's requirements, i.e. is compatible with the matrix polymer, is biocompatible, and is readily available because it is already being used, which would also reduce the price of the composite material because it could be purchased in bulk. The examiner further notes that it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Lesin, 125 USPZ 416. Applicant points out that Turner teaches that fibers of a **different** composition can be used. The examiner disagrees with applicant's interpretation of this phrase. It seems that applicant asserts that this is a teaching of the use of a fiber composed of a different polymer than that of the matrix composition. However, it appears to the examiner that this is a teaching of the use of a mixture of fibers composed of different materials from each other within the matrix polymer and has nothing to do with a comparison between

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the polymer compositions of the fiber and the matrix. Claim 1 is therefore rendered obvious for reasons set forth above.

With respect to the newly added limitation of claim 2, Turner discloses using fibers having a length anticipating applicants claimed length (example 2).

With respect to the newly added limitation of claim 4, Turner discloses the use of a filler, but does not appear to disclose the particular range claimed by applicant. It would have been obvious to one having ordinary skill in the art at the time the invention was made to vary the amount of filler, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

With respect to claims 19-21, it is the examiners position that if the properties claimed by applicant were not inherent in the composite of Turner than it would have been obvious to one having ordinary skill in the art at the time the invention was made to vary the flexural ductility, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

With respect to claim 25, Applicant appears to be claiming a process of hot compaction. This process is disclosed as being know in the art by applicant on pages 2-3, lines 15-10 of applicant's specification. It would have been obvious to a person of ordinary skill in the art to utilize this process to produce the composite material of Turner. Such a modification would have been motivated by the reasoned expectation of using a process that allows for preferential surface melting.

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With respect to claims 62-65, applicant discloses that it is known in the art to utilize a homo- or co-polymer of a polyolefin in a prosthetic component (p.1, lines 13-14). The polyolefin in the reference disclosed by applicant inherently has a molecular weight anticipating applicant's claimed molecular weight. It would have been obvious to a person of ordinary skill in the art to utilize the polyolefin disclosed by applicant in the composite of Turner, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Lesin, 125 USPZ 416.

With respect to claim 66, the process of making a fiber is not germane the patentability of the fiber itself.

10. Claims 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turner (4662887) in view of Dorman et al (4842604), as set forth in the last office action.

Turner renders obvious all elements of claim 6 as set forth above. Turner fails to teach the use of said biocompatible material to be apatite or hydroxyapatite. Dorman teaches the use of this element. Applicant first argues that there is no motivation to utilize the apatite taught by Dorman in the composite of Turner. However, Dorman teaches that these materials are desirable because they are biocompatible and result in tissue regrowth (col. 5, lines 32-47). Turner teaches the use of both a fibrous and particulate material to be used in his composite (col. 3, lines 33-35). Therefore, the combination of Turner and Dorman still provides for a reinforcing material, i.e. fiber, with

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the added benefits of Dorman's particulate material. Dorman also teaches the use of apatite in amounts up to 60% (col. 5, lines 39-41).

Applicant also argues that Turner and Dorman are non-analogous art. The examiner points out that both references are drawn to the creation of composite prosthetic materials. Said rejection is maintained from the last office action.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher Pratt whose telephone number is 703-305-6559. The examiner can normally be reached on Monday - Friday from 7 am to 4 pm.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Terrel Morris can be reached on 703-308-2414. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-2351.

Christopher C. Pratt
October 9, 2000



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